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10/576,631	04/16/2007	Stephen O'Hara	63162US005	5768

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
01/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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Office Action Summary	Application No.	Applicant(s)	
	10/576,631	O'HARA, STEPHEN	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 10/20/08 has been entered into the record. Claims 1-15 are pending and are under examination.

Information Disclosure Statement

The information disclosure statement filed 7/8/08 has been considered and an initialed copy is enclosed.

Rejections Withdrawn

The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Zolopa et al. (Ann Intern Med 1999; 131:813-821) is withdrawn in view of the amendment to the claims.

The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Kain et al. (Am. J. Trop. Med. Hyg., 49: 478-484, 1993) is withdrawn in view of the amendment to the claims.

The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Troesch et al. (Journal of Clinical Microbiology, Jan. 1999, p. 49-55) is withdrawn in view of the amendment to the claims.

The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Rustad et al. (Microbiology 148:1061-1072, 2002) is withdrawn in view of the amendment to the claims.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 13-15 rejected under 35 U.S.C. 102(b) as being anticipated by Peck et al. US 5,789,173 Aug. 4 1998.

The claims are drawn to a process for analyzing a biological sample, comprising the steps of:

(a) identifying a micro-organism present within the sample; and

(b) determining the effect of one or more antimicrobial(s) on a micro-organism from the sample, wherein determining the effect of one or more antimicrobials comprises adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of microorganisms in the sample at the end of the pre-determined time period;

wherein steps (a) and (b) are performed by analyzing the micro-organism's nucleic acid.

As to claim 1, Peck et al teaches a process for analyzing a biological sample (human body fluids, blood), comprising:

Incubating specimens of said samples in media embedded with antimicrobial agents of serial dilution concentration (pre-determined concentration) for a short time (pre-determined time period) to create differential microbial counts and amplifying the differential microbial counts by in vitro microbial DNA replication (assessing the number of microorganisms in the sample at the end of the pre-determined time period and analyzing the micro-organism's nucleic acid). See column 3 lines 18-34 and lines 56-61. Peck teaches step instant step (a) involving identifying a microorganism present within said sample by analyzing the microorganism's nucleic acid in column 2 lines 17-21… "identification of the pathogen, however, can be done in parallel by conventional methods, if necessary" and column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed".

As to claim 2-5, Peck et al teaches step a and step involving nucleic acid hybridization assay involving DNA amplification from the microorganism using polymerase chain reaction PCR. See DNA amplification primers in column 4 lines 38-45, column 5 lines 56-67 to column 6 lines 1-4, column 10 claims 1 and 11-13).

As to claim 6, Peck et al teaches primers specific to microorganism of interest column 4 lines 38-45 and column 10 claims 17-18.

As to claim 7-9, Peck et al teaches analyzing of the microorganism's DNA and 16S rRNA wherein the RNA is rRNA. See column 10 claim 17...wherein in vitro DNA replication amplifies a target DNA nucleotide sequence which encodes for the 16S rRNA gene.

As to claim 10, Peck et al teaches step A as set forth above and teaches that specimens from different human systems require different treatments and teaches the removal of pathogens from blood and precipitation of pathogens from blood (column 4 lines 46-47 and lines 52-58).

As to claim 13, Peck et al teaches instant step a and instant step as set forth above and teaches comparison step a and step b : column 2 lines 17-21… "identification of the pathogen, however, can be done in parallel by conventional methods, if necessary" and column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed" (i.e. a control well without antibiotics but with DNA amplification primers specific for fungi and mycobacteria).

As to claim 14, Peck et al teaches that the microorganism is a fungi or a bacterium: column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed"

As to claim 15, Peck et al teaches that the antimicrobial is an antibiotic or an antimycotic (antifungal such as fluconazole, nystatin or amphotericin b). See column 4 lines 24-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998.

The claims are drawn to a process for analyzing a biological sample, comprising the steps of:

(a) identifying a micro-organism present within the sample; and

(b) determining the effect of one or more antimicrobial(s) on a micro-organism from the sample, wherein determining the effect of one or more antimicrobials comprises adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of microorganisms in the sample at the end of the pre-determined time period;

wherein steps (a) and (b) are performed by analyzing the micro-organism's nucleic acid.

Peck et al teaches a process for analyzing a biological sample (human body fluids, blood), comprising:

Incubating specimens of said samples in media embedded with antimicrobial agents of serial dilution concentration (pre-determined concentration) for a short time (pre-determined time period) to create differential microbial counts and amplifying the differential microbial counts by in vitro microbial DNA replication (assessing the number of microorganisms in the sample at the end of the pre-determined time period and analyzing the micro-organism's nucleic acid). See column 3 lines 18-34 and lines 56-61. Peck teaches step instant step (a) involving identifying a microorganism present within said sample by analyzing the microorganism's nucleic acid in column 2 lines 17-21… "identification of the pathogen, however, can be done in parallel by conventional methods, if necessary" and column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed".

As to claim 2-5, Peck et al teaches step a and step involving nucleic acid hybridization assay involving DNA amplification from the microorganism using polymerase chain reaction PCR. See DNA amplification primers in column 4 lines 38-45, column 5 lines 56-67 to column 6 lines 1-4, column 10 claims 1 and 11-13).

As to claim 6, Peck et al teaches primers specific to microorganism of interest column 4 lines 38-45 and column 10 claims 17-18.

As to claim 7-9, Peck et al teaches analyzing of the microorganism's DNA and 16S rRNA wherein the RNA is rRNA. See column 10 claim 17...wherein in vitro DNA replication amplifies a target DNA nucleotide sequence which encodes for the 16S rRNA gene.

As to claim 10, Peck et al teaches step A as set forth above and teaches that specimens from different human systems require different treatments and teaches the removal of pathogens from blood and precipitation of pathogens from blood (column 4 lines 46-47 and lines 52-58).

As to claim 13, Peck et al teaches instant step a and instant step as set forth above and teaches comparison step a and step b : column 2 lines 17-21… "identification of the pathogen, however, can be done in parallel by conventional methods, if necessary" and column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed" (i.e. a control well without antibiotics but with DNA amplification primers specific for fungi and mycobacteria).

As to claim 14, Peck et al teaches that the microorganism is a fungi or a bacterium: column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed"

As to claim 15, Peck et al teaches that the antimicrobial is an antibiotic or an antimycotic (antifungal such as fluconazole nystatin or amphotericin b). See column 4 lines 24-33).

As to claim 12, Peck et al differs in that the reference does not teach that antimicrobials used in step (b) are selected based on the results of step a.

However, claim 12 would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made based on the teachings of Peck et al. Since Peck et

al teaches antimicrobial susceptibility testing and teaches that in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested, two micro-wells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed, it would have been prima facie obvious to first distinguish whether the samples contain fungi or mycobacteria using the microorganism specific DNA amplification primers and then perform the antimicrobial susceptibility testing using antifungal or antibiotic depending on the results of the DNA amplification. The method of Peck et al is modified in this manner to save time and resources (antimicrobials) in that the right type of antimicrobial (antifungal vs. antibiotic) is used for the antimicrobial susceptibility testing.

Claims 1-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998 in view of Bruno et al. Journal of Molecular Recognition, Vol. 9, 474-479 (1996) cited in IDS.

The claims are drawn to a process for analyzing a biological sample, comprising the steps of:

(a) identifying a micro-organism present within the sample; and

(b) determining the effect of one or more antimicrobial(s) on a micro-organism from the sample, wherein determining the effect of one or more antimicrobials comprises adding an antimicrobial at a pre-determined concentration to a sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the micro-organism, and assessing the number of microorganisms in

the sample at the end of the pre-determined time period;

wherein steps (a) and (b) are performed by analyzing the micro-organism's nucleic acid.

Peck et al teaches a process for analyzing a biological sample (human body fluids, blood), comprising:

Incubating specimens of said samples in media embedded with antimicrobial agents of serial dilution concentration (pre-determined concentration) for a short time (pre-determined time period) to create differential microbial counts and amplifying the differential microbial counts by in vitro microbial DNA replication (assessing the number of microorganisms in the sample at the end of the pre-determined time period and analyzing the micro-organism's nucleic acid). See column 3 lines 18-34 and lines 56-61. Peck teaches step instant step (a) involving identifying a microorganism present within said sample by analyzing the microorganism's nucleic acid in column 2 lines 17-21… "identification of the pathogen, however, can be done in parallel by conventional methods, if necessary" and column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed".

As to claim 2-5, Peck et al teaches step a and step involving nucleic acid hybridization assay involving DNA amplification from the microorganism using polymerase chain reaction PCR. See DNA amplification primers in column 4 lines 38-45, column 5 lines 56-67 to column 6 lines 1-4, column 10 claims 1 and 11-13).

As to claim 6, Peck et al teaches primers specific to microorganism of interest column 4 lines 38-45 and column 10 claims 17-18.

As to claim 7-9, Peck et al teaches analyzing of the microorganism's DNA and 16S rRNA wherein the RNA is rRNA. See column 10 claim 17...wherein in vitro DNA replication amplifies a target DNA nucleotide sequence which encodes for the 16S rRNA gene.

As to claim 10, Peck et al teaches step A as set forth above and teaches that specimens from different human systems require different treatments and teaches the removal of pathogens from blood and precipitation of pathogens from blood (column 4 lines 46-47 and lines 52-58).

As to claim 13, Peck et al teaches instant step a and instant step as set forth above and teaches comparison step a and step b : column 2 lines 17-21… "identification of the pathogen, however, can be done in parallel by conventional methods, if necessary" and column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed" (i.e. a control well without antibiotics but with DNA amplification primers specific for fungi and mycobacteria).

As to claim 14, Peck et al teaches that the microorganism is a fungi or a bacterium: column 4 lines 38-45: …in order to distinguish bacterial infection from fungal or mycobacterial infection when the results show resistance to all the antibacterial agents being tested two microwells containing no antibiotics but DNA amplification primers specific to fungi and mycobacteria respectively, are needed"

As to claim 15, Peck et al teaches that the antimicrobial is an antibiotic or an antimycotic (antifungal such as fluconazole nystatin or amphotericin b). See column 4 lines 24-33).

Although Peck teaches the removal of pathogens from blood and precipitation of pathogens from blood (column 4 lines 46-47 and lines 52-58), Peck et al does not teach removal of pathogens/microorganisms from blood by immunomagnetic separation.

Bruno et al teaches that immunomagnetic separation and concentration of specific target ligands or particles, such as bacteria ... from complex mixtures such as ... blood… is a widely accepted technique. See first sentence of abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to separate pathogen/microorganisms from blood in the method of Peck et al using immunomagnetic separation because Bruno et al teaches that immunomagnetic separation and concentration of specific target ligands or particles, such as bacteria from complex mixtures such as blood is a known and widely accepted technique. Thus, resulting in the instant invention with a reasonable expectation of success.

Status of Claims

Claims 1-15 is rejected. No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor Robert Mondesi (571-272-0956) can be contacted.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645